REMARKS

Claims 11-17 are pending in the present application. Claims 1-10 are canceled. Claims 11, 13, 14, 16-17 are amended to delete the genus *Daucus* and the species *Oenanthe javanica* and *Angelica pubescens* from the claims. No new matter is entered by way of this amendment.

Objections to the Specification

The Examiner objects to the title of the specification because the title is allegedly not descriptive. The title is amended to recite "Compositions Containing Plant Extracts For Treating Insulin-Related Diseases." This title is indicative of the invention to which the claims are directed. Accordingly, Applicants respectfully request the objection be withdrawn.

Claim Objections

The Examiner objects to claims 11-17 due to the misspelling of *Angelica pubescens*. The claims are amended and do not recite the misspelled species. Accordingly, Applicants respectfully request the objection be withdrawn.

Rejections under 35 USC §112

Claim Rejections under 35 USC §112, first paragraph

Claims 11-12 and 14-15 are rejected under 35 USC § 112, first paragraph because the specification, although enabled for an insulin-mimetic action agent, an agent for the enhancement of glucose uptake in a cell, and an agent for the induction of adipocyte differentiation, does not reasonably provide enablement for plant extracts used to treat disorders associated with an abnormal response to insulin or abnormal insulin levels. Applicants respectfully traverse.

Specifically, the Examiner asserts that the specification does not enable all of the many disorders and diseases that are associated with aberrant insulin response or aberrant insulin levels. Applicants submit that the Examiner has not provided sufficient evidence to support her assertions.

In order to establish a *prima facie* case of non-enablement, the Examiner must explain why the specification is not enabled based on sound scientific reasoning or acceptable evidence, which is inconsistent with statements in the specification asserting enablement. (*In re Marzocchi*, 169 USPQ 367 (CCPA 1971). For the reasons set forth below, Applicants contend that the Examiner has not established such reasoning or evidence.

1. The specification provides working examples demonstrating efficacy.

First of all, the Examiner asserts that the specification is not enabling because no working examples are provided that demonstrate the efficacy of the claimed plant extracts in treating insulin-related diseases (page 5 of the present Office Action). However, Example 26 on page 55, in the specification as filed, demonstrates the efficacy of the inventive agents in treating diabetes, and insulin-related disease. Example 26 shows that when 5 mL/kg of *Angelica keiskei* koidz extract is administered for seven days to type II diabetes model mice, the mice' blood glucose levels are remarkably lowered. Thus, as Applicants assert in the specification, the inventive extracts are useful to ameliorate the effects of insulin-related diseases, such as diabetes (page 55, lines 9-10).

Moreover, Applicants are not obligated to provide an exhaustive number of working examples to show enablement. Enablement can be provided through broad terminology or illustrative examples. *In re Marzocchi*, id at 369.

2. The specification describes dosages that may be used to treat insulin-related disorders.

Furthermore, the Examiner, also, is incorrect in asserting that "nowhere in the specification...does Applicant direct the claimed subject matter to the administration of compositions comprising an extract of a plant...as an effective ingredient in any subject." (Office Action, page 6). In contrast to the Examiner's assertion, the specification does teach how to administer the inventive extracts, as well as how to make them.

Particularly, Applicants have provided numerous examples of how to make the instant extracts (See, *e.g.* Examples 1, 2, 6, 8, 11, 14, 22, 24, and 25). Additionally, the specification teaches methods for the administration, dosage level, dosage form and formulation of these inventive extracts, and also provides guidance by teaching preferred methods. (See, *e.g.* pages 13 at lines 17 through to page 16 at line 22 in the specification as filed). Specifically, with respect to formulations, the specification teaches that the dose of the inventive agents is about 0.1 μg to 1 g/kg weight for humans per day (page 16) and preferably 0.01 mg to 2000 mg, per day per 1 kg of the body weight of a subject organism (page 23 at lines 18-21). Furthermore, page 14 in the instant specification provides guidance on particular pharmaceutical carriers and adjuvants used in formulations. The specification, also, teaches that the optimal dosages to be administered will vary and may be determined by those skilled in the art depending on a variety of factors which are listed thereafter (page 14 at lines 7-20). Thus, we contend that the specification is sufficiently enabled such that a skilled artisan recognizes how to make the inventive extracts and how to use them to treat insulin-related disorders.

3. The Shimura reference is not contrary to Applicants assertion regarding enablement.

Furthermore, the Examiner does not provide any objective evidence that would cause a skilled artisan to doubt that the inventive plant extracts may be used to treat insulin-related disorders. Although the Examiner cites Japanese Patent No. 05-255100 to Shimura ("Shimura") to support her contention that the art is unpredictable, this reference only acts to support Applicants' statements. The Shimura reference discloses that *Angelica pubescens* extract may be used to treat obesity. (See, abstract on page 2 of the Shimura reference). Thus, although the Shimura reference allegedly fails to describe an efficacious dose of *Angelica pubescens* or provide any *in vivo* examples, this reference does not contradict Applicants' assertion that the present agents may be used to treat insulin-related disorders.

Therefore, Applicants contend that by following the guidance provided in the instant specification, the skilled artisan understands how to make the inventive plant extracts, as well as how to use them to treat subjects having insulin related disorders or as a prophylactic against such disorders. Thus, one of ordinary skill can practice the claimed invention without undue experimentation. Therefore, Applicants submit that the specification enables claims 11-12 and 14-15 and request that the rejection be withdrawn.

Issues under 35 USC §102

Cho

Claims 11, 12, 14 and 15 are rejected under 35 USC § 102(b) as being anticipated by Japanese Patent No. 2001-039882 to Cho ("Cho"). Applicants respectfully traverse.

Claims 11 and 14 are drawn to a therapeutic agent or prophylactic agent , or a food, beverage, or feed, respectively, for treating or preventing a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the agent comprises an extract of a plant selected from the group consisting of *Angelica keiskei* koidz., *Apium,* and *Cryptotaenia japonica Hassk* as an effective ingredient.

In contrast, Cho discloses a preparation for treating diabetes in the form of a drug or a health food comprising *Daucus carota* L. Therefore, Cho fails to disclose all of the elements of independent claims 11 or 14.

Specifically, the Cho reference fails to disclose the elements of *Angelica keiskei* koidz., *Apium,* and *Cryptotaenia japonica Hassk* as an effective ingredient. Therefore, the Cho reference does not anticipate independent claims 11 and 14 and dependents thereof. Accordingly, Applicants respectfully request the rejection be withdrawn.

Shimura

Claims 11, 12 and 17 under 35 USC § 102(b) as being anticipated by Japanese Patent No. 05-255100 to Shimura ("Shimura"). Applicants respectfully traverse.

Claims 11 is drawn to a therapeutic agent or prophylactic agent for treating or preventing a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the agent comprises an extract of a plant selected from the group consisting of *Angelica keiskei* koidz., *Apium,* and *Cryptotaenia japonica Hassk* as an effective ingredient.

Claim 17 is drawn to an agent for the induction of adipocyte differentiation, comprising an extract of a plant selected from the group consisting of *Angelica keiskei* koidz., *Apium,* and *Cryptotaenia japonica Hassk* as an effective ingredient.

In contrast, Shimura discloses a lipase inhibitor comprising active substances extracted from *Angelica pubescens* for preventing or suppressing obesity and which check lipase activity. Therefore, Shimura fails to disclose all of the elements of claims 11 and 17.

Specifically, the Shimura reference fails to disclose the elements of *Angelica keiskei* koidz., *Apium* and *Cryptotaenia japonica Hassk* as an effective ingredient. Therefore, the Shimura reference does not anticipate independent claims 11 and 17 and dependents thereof. Accordingly, Applicants respectfully request the rejection be withdrawn.

Yang et al.

Claims 13 and 16 are rejected under 35 USC § 102(b) as being anticipated by the abstract of Yang *et al.*, *Acta Pharmacol Sin.* (2000): 21 pp 239-242. ("Yang *et al*"). Applicants respectfully traverse.

Claim 13 is drawn to an insulin-mimetic action agent, wherein the agent comprises an extract of a plant selected from the group consisting of *Angelica keiskei* koidz., *Apium* and *Cryptotaenia japonica Hassk* as an effective ingredient.

Claim 16 is drawn to an agent for the enhancement of glucose uptake into a cell, comprising an extract of a plant selected from the group consisting of *Angelica keiskei* koidz., *Apium* and *Cryptotaenia japonica Hassk* as an effective ingredient.

In contrast, Yang *et al.* teaches the extract of *Oenanthe javanica* for the treatment of diabetes, which possesses hypoglycemic and hypotriglyceride action and promotes the release of insulin. Thus, the Yang *et al.* reference does not teach all of the elements of independent claims 13 and 16.

Specifically, the Yang *et al.* reference fails to disclose the elements of *Angelica keiskei* koidz., *Apium* and *Cryptotaenia japonica Hassk* as an effective ingredient. Therefore, the Yang *et al.* reference does not anticipate claims 13 and 16. Accordingly, Applicants respectfully request the rejection be withdrawn.

Obviousness-Type Double Patenting

Claim 14 is provisionally rejected for obvious-type double patenting over claim 22 of Application No. 10/257,321 ('321). The '321 application is abandoned. Accordingly, this rejection is moot.

Claims 11 and 14 stand provisionally rejected by the Examiner under the judicially created doctrine of double patenting over claims 1 and 7 of application No. 10/483,491 ('491). Applicants respectfully traverse.

A "provisional" double patenting rejection should continue to made by the Examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the Examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. See MPEP 804(I) (B). Accordingly, no action need be taken by Applicants at this time.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

If the Examiner has any questions concerning this application, the Examiner is requested to contact Marc S. Weiner, Reg. No. 32,181 at the telephone number of (703) 205-8000.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

By #42,874

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